

**REMARKS**

Applicants submit this response to a Notice of Non-Compliant Amendment mailed on January 05, 2004. This response is a duplicate of an amendment filed by applicants on November 26, 2003. In that amendment, applicants inadvertently did not include a complete listing of all claims in the present application - omitting to list withdrawn claims. By this response, applicants have included a complete listing of all claims of the present application.

In the Office Action, the Examiner has rejected 1-3, 17-18, 26-29, 41-42, 50, 51, 53-55, 61, 64, 65 and 73 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,834,704 to Reinicke. Applicants respectfully traverse that rejection.

Reinicke is directed to an apparatus for implanting a medication reservoir in a cavity of an animal to facilitate long-term infusion of medication (up to hundreds of days). See, e.g., Abstract. Reinicke discloses making an injection into the peritoneal cavity or other like cavity, with the penetration depth of the needle cannula being limited to about one inch or less. Although not expressly disclosed, it is obvious that the penetration depth must be greater than the skin thickness of the animal (disclosed as a cow or hog), and must also be great enough to penetrate completely through the dermis layer and enter the peritoneal or other similar cavity. A penetration depth limited to the intradermal space would render the apparatus disclosed by Reinicke useless, as a cavity is required to deposit the medication reservoir.

Applicants' invention, in contrast, is directed to an intradermal needle assembly that limits penetration of a needle into the skin of a patient during injection to ensure that the drug substance being injected is injected in to the dermis layer of the patient's skin. It is known that

the dermis layer of a human's skin is generally in the range of 0.5 mm to 3 mm (variations exist from person to person, and even from area to area on the same person). Applicants respectfully submit that the disclosure of Reinicke of a penetration depth of about one inch or less is not a disclosure of sufficient specificity to constitute an anticipatory reference under 35 U.S.C. §102. See, e.g., MPEP §2131.03. Applicants' claims are directed to a relatively narrow range, while the disclosure of Reinicke teaches a relatively broad range. When considered in its entirety, as is required of a prior art reference (see., e.g., *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983, *cert. Denied*, 496 U.S. 851 (1084)), the disclosure of Reinicke cannot be considered to disclose the range claimed by applicants. More specifically, Reinicke teaches limiting an injection depth to about one inch or less, provided that the injection depth is sufficient to deposit a reservoir in a suitable body cavity. In order for that to occur, the injection depth must exceed the skin thickness of the animal, and certainly cannot limit the injection depth to the dermis layer of the skin. Such an interpretation of the teaching of Reinicke would render that invention inoperable. Thus, applicants respectfully submit that Reinicke does not teach or suggest their invention. More specifically, Reinicke does not disclose or suggest an intradermal needle assembly, as defined by applicants' claim 1, for example, comprising, *inter alia*, a needle cannula having a forward tip that extends beyond a generally flat skin engaging surface a distance ranging from 0.5 mm to 3.0 mm.

Applicants respectfully submit that Reinicke fails to teach every limitation recited by the claims of the present application, as is necessary of a proper 35 U.S.C. §102 reference. Thus, in view of the distinguishing points set forth above, applicant respectfully submits that the

Examiner's rejection is no longer tenable, and applicant respectfully requests withdrawal of that rejection.

The Examiner also rejected claims 24-25, 48-49 and 71-72 under 35 U.S.C. §103(a) as being unpatentable over Reinicke in view of U.S. Patent No. 5,672,883 to Reich. Applicants respectfully traverse that rejection. Reich is directed to a container and method for transporting a syringe containing radioactive material. Reich fails to disclose or suggest the deficiencies identified above with regard to Reinicke, and therefore the Examiner's proposed combination of those references does not render applicants' invention unpatentable. Thus, applicants respectfully submit that their invention is not obvious in view of the Examiner's proposed combination of Reinicke and Reich. Applicants further submit that the Examiner's rejection of claims 24-25, 48-49 and 71-72 under 35 U.S.C. §103(a) as being unpatentable over Reinicke in view of Reich is no longer tenable, and respectfully request withdrawal of that rejection.

Applicants acknowledge and appreciate the Examiner's indication of the allowability of claims 5-10, 31-35, 56-58 and 62-63. However, in view of the distinguishing remarks set forth above, applicants respectfully submit that all claims pending in the present application are now in condition for allowance, and request prompt allowance thereof.

Applicant hereby authorizes the Commissioner to charge the fees necessary in connection with this Amendment and any other fees necessary in connection with this application, to Deposit Account Number 02-1666.

Application Serial No.: 09-4,438  
Response Dated February 02, 2004  
Reply To Notice of Non-Compliant Amendment

Any questions concerning this application or amendment may be directed to the undersigned agent of applicant.

Respectfully submitted,

Dated: February 02, 2004

By: David Fortunato  
David M. Fortunato  
Attorney for Applicant(s)  
Reg. No. 42,548  
(201) 847-6940